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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Our Case No. 98,736)

Application of:

Roderick L. Hall, et al.

Serial No.: 09/218,913

Filed: December 22, 1998

For: A METHOD FOR ACCELERATING
THE RATE OF MUCOCILIARY
CLEARANCE

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) Examiner: To be assigned
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) Group Art Unit: To be assigned
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TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In regard to the above identified application:

1. We are transmitting herewith the attached:

- a. Supplemental Information Disclosure Statement;
- b. U.S. PTO Form 1449;
- c. Copies of 16 references;
- d. Return postcard.

2. With respect to additional fees:

No fee is required.

3. General Authorization: Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is attached.
4. **CERTIFICATE OF MAILING UNDER 37 CFR § 1.8**: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231 on this 21 day of January, 1999.

Dated: 1/21/99

Respectfully submitted,

Emily Miao

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Reg. No. 35,285

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(Our Case No. 98,736)

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In order to comply with discretionary regulations 37 CFR 1.97 and 1.98, attached hereto is Form PTO-1449, and copies¹ of the documents listed thereon. These documents contain information which the Examiner may consider to be important in deciding whether to allow the present application to issue as a patent.

1. Newton, B.B. and Hall, R.L. Mucociliary clearance in the guinea-pig is increased by ouabain (i.v.) and by hypertonic saline (14.4%) aerosol. in *Cilia, Mucus and Mucociliary Interactions*. Ed. Baum, G.L., Priel, Z., Roth, Y., Liron, N., Ostfeld, E., Marcel Dekker. New York. 1998.

¹To the extent that a document is listed and no copy of same is attached, then such document is not at the present time available to the undersigned or is available in the file of a parent application. If a listed document is not in the English language and an English translation is readily available, such translation is also attached; if translation is not attached it is not readily available to the undersigned. If a foreign language patent document is cited, and an English language equivalent is known to the undersigned, then such equivalent patent is also cited on the attached form along with the corresponding foreign language patent and a connecting arrow indicated therebetween; if no such English language equivalent is cited, then none is known to the undersigned.

2. Wills, P.J., Garcia Suarez, M.J., Rutman, A., Wilson, R., and Cole, P.J. The ciliary transportability of sputum is slow on the mucus-depleted bovine trachea. *American Journal of Respiratory & Critical Care Medicine* 151(4):1255-1258, 1995.
3. Wills, P.J., Hall, R.L., Chan, W.M., and Cole, P.J. Sodium chloride increases the ciliary transportability of cystic fibrosis and bronchiectasis sputum on the mucus-depleted bovine trachea. *Journal of Clinical Investigation* 97(11):9-13, 1997.
4. Mathews, L.W., Spector, S., Lemm, J., and Potter, J.L. Studies on Pulmonary secretions. I. The Overall Chemical Composition of Pulmonary Secretions from Patients with Cystic Fibrosis, Bronchiectasis, and Laryngectomy. *American Review of Respiratory Disease* 88:199-204, 1963.
5. Potter, J.L., Matthews, L.W., Spector, S., and Lemm, J. Studies on pulmonary secretions. II. Osmolality and the ionic environment of pulmonary secretions from patients with cystic fibrosis, bronchiectasis, and laryngectomy. *American Review of Respiratory Disease* 67(1):83-87, 1967.
6. Tomkiewicz, R.P., App, E.M., Zayas, J.G., Ramirez, O., Church, N., Boucher, R.C., Knowles, M.R., and King, M. Amiloride inhalation therapy in cystic fibrosis. Influence on ion content, hydration, and rheology of sputum. *American Review of Respiratory Disease* 148(4 Pt 1):1002-1007, 1993.
7. Robinson, M., Hemming, A.L., Regnis, J.A., Wong, A.G., Bailey, D.L., Bautovich, G.J., King, M., and Bye, P.T.P. Effect of increasing doses of hypertonic saline on mucociliary clearance in patients with cystic fibrosis. *Thorax* 52(10):900-903, 1997.
8. App, E.M., King, M., Helfesrieder, R., Kohler, D., and Matthys, H. (1990) Acute and long-term amiloride inhalation in cystic fibrosis lung disease. A rational approach to cystic fibrosis therapy. *American Review of Respiratory Disease* 141, 605-612.
9. Newton, B.B., Poll, C.T. and Hall, R.L. Inhalation of amiloride increases tracheal mucus velocity and decreases tracheal potential difference in the guinea-pig. *Pediatric Pulmonology* S17, Abs 364, 1998.
10. McAulay, A.E., Crossley, J., Place, G.A. and Poll, C.T. Effect of UTP on ion transport in tertiary cultures of human bronchial epithelial (HBE) cells. *Pediatric Pulmonology* S 17, Abs 141, 1998.
11. Vallet, V., Chraibi, A., Gaeggeler, H.P., Horisberger, J.D., and Rossier, B.C. An epithelial serine protease activates the amiloride-sensitive sodium channel. *Nature* 389(6651):607-610, 1997.

12. Chraibi, A., Vallet, V., Firsov, D., Hess, S.K., and Horisberger, J.D. Protease modulation of the activity of the epithelial sodium channel expressed in xenopus oocytes. *Journal of General Physiology* 111(1): 127-138, 1998.
13. Delaria, K.A., Muller, D.K., Marlor, C.W., Brown, J.E., Das, R.C., Roczniak, S.O. and Tamburini, P.P. Characterization of placental bikunin, a novel serine protease inhibitor. *Journal of Biological Chemistry* 272(18):12209-12214, 1997.
14. Marlor, C.W., Delaria, K.A., Davis, G., Muller, D.K., Greve, J.M., and Tamburini, P.P. Identification and cloning of human placental bikunin, a novel serine protease inhibitor containing two kunitz domains. *Journal of Biological Chemistry* 272(18):12202-12208, 1997.
15. O'Riordan, T.G., Otero, R., Mao, Y.M., Lauredo, I., and Abraham, W.M. Elastase contributes to antigen-induced mucociliary dysfunction in ovine airways. *American Journal of Respiratory & Critical Care Medicine* 97(5):1522-1528, 1997.
16. O'Riordan, T.G., Mao, Y.M., Otero, R., Lopez, J., Sabater, J.R., and Abraham, W.M. Budesonide affects allergic mucociliary dysfunction. *Journal of Applied Physiology* 85(3):1086-1091, 1998.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Supplemental Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56 insofar as an Examiner might consider any of the cited documents important in deciding whether to allow the application to issue as a patent, but the citation of each document is not to be construed as an admission that such document is necessarily relevant

or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Date:

1/21/99



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